IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

BARBARA J. GONZALEZ and CARLOS M. GONZALEZ,	)	**CASE NO.**
Plaintiffs,	)	
v.	)	
PFIZER INC.,	)	**COMPLAINT AND DEMAND FOR JURY TRIAL**
Defendant.	)	

The Plaintiffs, Barbara J. Gonzalez (the Lipitor user who is referred to individually herein as "Plaintiff") and Carolos M. Gonzalez, residing in Memphis, Tennessee, by and through their undersigned attorneys, hereby sue the Defendant, Pfizer Inc. ("Defendant" or "Pfizer"), which has its principal place of business at 235 East 42nd Street, New York, New York 10017, and alleges as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiffs as a direct and proximate result of Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of LIPITOR (also known as ATORVASTATIN CALCIUM and at times referred to herein as "the subject product").

PARTIES

2. Plaintiffs are natural persons and residents of the State of Tennessee.

3. At all times herein mentioned, Defendant was and is a corporation existing under the laws of incorporation of the State of Delaware, with its principal place of business in New York, New York, and doing business within this judicial district.

4. At all times herein mentioned, Defendant Pfizer, in interstate commerce and in this judicial district, advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, LIPITOR.

JURISDICTION AND VENUE

5. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendant has significant contacts with this district by virtue of doing business within this judicial district.

6. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL ALLEGATIONS

7. At all times herein mentioned, Defendant, by and through its agents, servants, and/or employees failed to adequately warn physicians and consumers, including Plaintiff herein, of the risk of developing diabetes from LIPITOR.

8. LIPITOR is an HMG-CoA reductase inhibitor and a member of the drug class known as statins.

9. LIPITOR is prescribed to reduce the amount of cholesterol and other fatty substances in the blood.

10. Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company obtained approval from the Food and Drug Administration ("FDA") to market LIPITOR on December 17, 1996. Warner-Lambert entered into a co-marketing agreement with Pfizer to sell Lipitor, and thereafter those companies began distributing and selling Lipitor throughout the United States in 1997. On June 19, 2000, Pfizer acquired Warner-Lambert and all rights to Lipitor.

11. Despite its knowledge of data indicating that LIPITOR use is causally related to the development of type 2 diabetes and/or blood glucose levels diagnostic for type 2 diabetes, Pfizer promoted and marketed LIPITOR as safe and effective for persons such as Plaintiff throughout the United States, including this judicial district.

12. On August 11, 2011, the Division of Metabolism and Endocrinology Products of the FDA requested that Defendant make labeling changes for Lipitor based upon the FDA's comprehensive review, including clinical trial data.

13. In February 2012, Pfizer complied with the FDA request and added the following language to its Warnings and Precautions Section: "Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIPITOR."

14. Until the February 2012 change, LIPITOR's label had never warned patients of any potential relation between changes in blood sugar levels and taking LIPITOR.

15. Despite the February 2012 label change, LIPITOR's label continues to fail to warn consumers of the serious risk of developing type 2 diabetes per se when using LIPITOR.

16. At all times material hereto, Defendant knew or should have known that the risks of LIPITOR included the severe and life-threatening complications of type 2 diabetes.

17. At all times material hereto, Defendant, by and through its agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed, and/or sold LIPITOR without adequate instructions or warnings of the drug's serious side effects and unreasonably dangerous risks.

18. Plaintiff was prescribed LIPITOR and used it as directed from approximately May 1999 until approximately August 2008.

19. Plaintiff was prescribed LIPITOR to lower her levels of low-density lipoprotein ("LDL") and as a preventive measure to decrease her risk of developing cardiovascular disease ("CVD").

20. Plaintiff agreed to initiate LIPITOR treatment in an effort to reduce her risk of developing heart disease. She relied on claims made by Pfizer that LIPITOR has been clinically shown to reduce the risk of developing heart disease.

21. Plaintiff developed type 2 diabetes after initiating her LIPITOR treatment.

22. Plaintiff was diagnosed with type 2 diabetes in or about 2000. As a result, for the rest of her life she must undergo regular testing of her blood glucose levels, adhere to a restrictive diabetic diet, and take medication to control her diabetes. Due to her diabetes, she is now at markedly increased risk of heart disease, blindness, neuropathy, and kidney disease.

23. Had Defendant properly disclosed the risks associated with LIPITOR, Plaintiff would have avoided the risk of diabetes by either not using LIPITOR at all or by closely monitoring her blood glucose levels to see if the drug was adversely affecting her metabolism.

24. As alleged herein, as a direct, proximate, and legal result of Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug LIPITOR, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to type 2 diabetes. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FIRST CAUSE OF ACTION
[Product Liability – Failure to Warn]

25. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

26. Defendant has engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting LIPITOR, and through that conduct has knowingly and intentionally placed LIPITOR into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

27. Defendant did in fact sell, distribute, supply, manufacture, and/or promote LIPITOR to Plaintiff and to her prescribing physicians. Additionally, Defendant expected the LIPITOR that it was selling, distributing, supplying, manufacturing, and/or promoting to reach – and LIPITOR did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendant.

28. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendant and ingested by Plaintiff. The defective condition of LIPITOR was due

in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing diabetes as a result of its use.

29. This defect caused serious injury to Plaintiff, who used LIPITOR in its intended and foreseeable manner.

30. At all times herein mentioned, Defendant had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

31. Defendant so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

32. Defendant negligently and recklessly failed to warn of the nature and scope of the side effects associated with LIPITOR, namely diabetes.

33. Defendant was aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendant knew or should have known that LIPITOR caused serious injuries, it failed to exercise reasonable care to warn of the dangerous side effect of developing diabetes from LIPITOR use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendant willfully and deliberately failed to avoid the consequences associated with its failure to warn, and in doing so, Defendant acted with a conscious disregard for the safety of Plaintiff.

34. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

35. Defendant, as the manufacturer and/or distributor of the subject product, is held to the level of knowledge of an expert in the field.

36. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendant Pfizer.

37. Had Defendant properly disclosed the risks associated with LIPITOR, Plaintiff would have avoided the risk of diabetes by either not using LIPITOR at all or by closely monitoring her blood glucose levels to see if the drug was adversely affecting her metabolism.

38. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendant alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

SECOND CAUSE OF ACTION
[Negligence]

39. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

40. At all times material hereto, Defendant had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of LIPITOR.

41. Defendant breached its duty of reasonable care to Plaintiff in that it negligently promoted, marketed, distributed, and labeled the subject product.

42. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendant, including, but not limited to, one or more of the following particulars:

(a) In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of the subject product;

(b) In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of LIPITOR's dangerous and defective characteristics;

(c) In its design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

(d) In its promotion of the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause diabetes;

(e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

(f) In failing to perform appropriate pre-market testing of the subject product;

(g) In failing to perform appropriate post-market surveillance of the subject product;

(h) In failing to adequately and properly test LIPITOR before and after placing it on the market;

(i) In failing to conduct sufficient testing on LIPITOR which, if properly performed, would have shown that LIPITOR had the serious side effect of causing type 2 diabetes;

(j) In failing to adequately warn Plaintiff and her healthcare providers that the use of LIPITOR carried a risk of developing type 2 diabetes and that patients' blood glucose should be closely monitored;

(k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of diabetes associated with the use of LIPITOR; and

(l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely diabetes, from LIPITOR ingestion as described herein.

43. Defendant knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendant's failure to exercise reasonable and ordinary care.

44. As a direct and proximate result of Defendant's carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, type 2 diabetes. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

THIRD CAUSE OF ACTION
[Product Liability – Breach of Implied Warranty]

45. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

46. At all times mentioned herein, Defendant manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold LIPITOR,

and prior to the time that it was prescribed to Plaintiff, Defendant impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

47. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendant.

48. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

49. Due to Defendant's wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after she used it.

50. Contrary to the implied warranty for the subject product, LIPITOR was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

51. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, type 2 diabetes. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FOURTH CAUSE OF ACTION
[Fraud]

52. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

53. Defendant misrepresented to Plaintiff, her prescribing physicians, and the healthcare industry the safety and effectiveness of LIPITOR and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of LIPITOR.

54. Defendant made misrepresentations and actively concealed adverse information when Defendant knew, or should have known, that LIPITOR had defects, dangers, and characteristics that were other than what Defendant had represented to Plaintiff and the healthcare industry generally. Specifically, Defendant actively concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996 Defendant and/or its predecessors were in possession of data demonstrating that LIPITOR increases the risk of type 2 diabetes and the risk of increased blood glucose to levels diagnostic for type 2 diabetes;

(b) There had been insufficient studies by Defendant and/or its predecessors regarding the safety and efficacy of LIPITOR in women before and after its product launch;

(c) LIPITOR was not fully and adequately tested by Defendant and/or its predecessor for the risk of developing type 2 diabetes; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of LIPITOR increases the risk of type 2 diabetes.

55. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendant.

56. Defendant knew or should have known that these representations were false, and it made the representations with the intent or purpose of deceiving Plaintiff, her prescribing physicians, and the healthcare industry.

57. Defendant made these false representations with the intent or purpose that Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading to the use of LIPITOR by Plaintiff as well as the general public.

58. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the falsity of the statements being made by Defendant and believed them to be true. Had they been aware of said facts, her physicians would not have prescribed and Plaintiff would not have utilized the subject product.

59. Plaintiff justifiably relied on and/or was induced by Defendant's misrepresentations and/or active concealment and relied on the absence of safety information which Defendant did suppress, conceal, or fail to disclose to Plaintiff's detriment.

60. Defendant had a post-sale duty to warn Plaintiff, her prescribing physicians, and the general public about the potential risks and complications associated with LIPITOR in a timely manner.

61. Defendant made the representations and actively concealed information about the defects and dangers of LIPITOR with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting LIPITOR as a treatment.

62. As a result of the concealment and/or suppression of the facts set forth above, Plaintiff ingested LIPITOR and suffered injuries as set forth herein.

FIFTH CAUSE OF ACTION
[Constructive Fraud]

63. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

64. Defendant committed actual fraud by making material representations which were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and her prescribing physicians would rely on such material representations.

65. Plaintiff and her prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

66. Additionally, Defendant knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that it had a duty to inform Plaintiff, her prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and her prescribing physicians would rely on Defendant's misrepresentations. Plaintiff and her prescribing physicians did, in fact, act in actual and justifiable reliance on Defendant's representations, and Plaintiff was injured as a result.

67. At all times herein mentioned, Defendant had a duty to Plaintiff, her prescribing physicians, and the general public to accurately inform them of risks associated with its product LIPITOR because Defendant, as the manufacturer of the subject product, was in a position of superior knowledge and judgment regarding any potential risks associated with its product LIPITOR.

68. Defendant committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the LIPITOR at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

69. In breaching its duties to Plaintiff, Defendant used its position of trust as the manufacturer of LIPITOR to increase sales of the drug at the expense of informing Plaintiff that, by ingesting LIPITOR, she was placing herself at a significantly-increased risk of developing type 2 diabetes.

SIXTH CAUSE OF ACTION
[Unjust Enrichment]

70. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

71. Plaintiff conferred a benefit on Defendant by purchasing LIPITOR.

72. Plaintiff, however, did not receive a safe and effective drug for which she paid.

73. It would be inequitable for Defendant to retain this money because Plaintiff did not, in fact, receive a safe and efficacious drug.

74. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant has been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

SEVENTH CAUSE OF ACTION
[Punitive Damages]

75. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

76. At all times material hereto, Defendant knew or should have known that LIPITOR was inherently dangerous with respect to the risk of diabetes.

77. At all times material hereto, Defendant attempted to misrepresent and did misrepresent facts concerning the safety of LIPITOR.

78. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

79. At all times material hereto, Defendant knew and recklessly disregarded the fact that LIPITOR causes the chronic illness diabetes.

80. Notwithstanding the foregoing, Defendant continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

81. Defendant knew of the subject product's lack of warnings regarding the risk of diabetes, but it intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell LIPITOR without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by LIPITOR.

82. Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using LIPITOR against its benefits.

83. As a direct and proximate result of Defendant's willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of its consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, type 2 diabetes. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

84. Defendant's aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter it from similar conduct in the future.

EIGHTH CAUSE OF ACTION
[Loss of Consortium on behalf of Carlos M. Gonzalez]

85. Plaintiffs repeat and re-allege each and every allegation of this Complaint as if set forth in full in this cause of action.

86. Plaintiff Carolos M. Gonzalez was and is the lawful spouse of Plaintiff Barbara J. Gonzalez, and as such, was and is entitled to the comfort, enjoyment, society and services of his spouse.

87. As a direct and proximate result of the foregoing, Plaintiff Carlos M. Gonzalez was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff Barbara J. Gonzalez, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Carlos M. Gonzalez's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendant as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendant as follows:

(a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for LIPITOR;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of its conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Respectfully submitted,

By: **/s/ B.J. Wade**
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